

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 017876 ....	LOESTRIN 21 1/20 .....	Ethinyl Estradiol; Norethindrone Acetate.	0.02 mg; 1 mg .....	Tablet; Oral .....	Teva Branded Pharms.
NDA 018647 ....	CORZIDE .....	Bendroflumethiazide; Nadolol.	5 mg; 40 mg; 5 mg; 80 mg .....	Tablet; Oral .....	King Pharms., LLC.
NDA 018685 ....	GAVICON .....	Aluminum Hydroxide; Magnesium Trisilicate.	80 mg; 20 mg; 160 mg, 40 mg .....	Tablet; Oral .....	Chatterm.
NDA 018751 ....	SPECTAZOLE .....	Econazole Nitrate .....	1% .....	Cream; Topical .....	Alvogen, Inc.
NDA 019813 ....	DURAGESIC-100 .....	Fentanyl .....	100 Micrograms (mcg)/Hour; 12.5 mcg/Hour; 25 mcg/Hour; 37.5 mcg/Hour; 50 mcg/Hour; 75 mcg/Hour.	Film, Extended Release; Transdermal.	Janssen Pharms.
NDA 020519 ....	CICLOPIROX .....	Ciclopirox .....	0.77% .....	Gel; Topical .....	Alvogen, Inc.
NDA 021015 ....	ANDROGEL .....	Testosterone .....	25 mg/2.5 Grams (g) Packet; 50 mg/5 g Packet.	Gel; Transdermal .....	Besins Healthcare.
NDA 021152 ....	CUTIVATE .....	Fluticasone Propionate ..	0.05% .....	Lotion; Topical .....	Fougera Pharms.
NDA 021169 ....	RAZADYNE .....	Galantamine Hydrobromide.	Equivalent to (EQ) 4 mg Base; EQ 8 mg Base; EQ 12 mg Base.	Tablet; Oral .....	Janssen Pharms.
NDA 021567 ....	REYATAZ .....	Atazanavir Sulfate .....	EQ 150 mg Base .....	Capsule; Oral .....	Bristol Myers Squibb.
NDA 021695 ....	ANTARA (MICRONIZED).	Fenofibrate .....	30 mg .....	Capsule; Oral .....	Lupin.
NDA 022107 ....	TEKTRUNA HCT .....	Aliskiren Hemifumarate; Hydrochlorothiazide.	EQ 150 mg Base; 12.5 mg; EQ 150 mg Base; 25 mg; 300 mg; 12.5 mg; 300 mg; 25 mg.	Tablet; Oral .....	Noden Pharma.
NDA 022309 ....	ANDROGEL .....	Testosterone .....	1.62% (20.25 mg/1.25 g Packet); 1.62% (40.5 mg/2.5 g Packet).	Gel; Transdermal .....	Besins Healthcare.
NDA 022401 ....	TWYNSTA .....	Amlodipine Besylate; Telmisartan.	EQ 5 mg Base; 40 mg; EQ 10 mg Base; 40 mg; EQ 5 mg Base; 80 mg; EQ 10 mg Base; 80 mg.	Tablet; Oral .....	Boehringer Ingelheim.
NDA 022426 ....	OSANI .....	Alogliptin Benzoate; Pioglitazone Hydrochloride.	EQ 12.5 mg Base; EQ 15 mg Base; EQ 12.5 mg Base; EQ 45 mg Base.	Tablet; Oral .....	Takeda Pharms. USA.
NDA 050824 ....	OMEPRAZOLE AND CLARITHROMYCIN AND AMOXICILLIN.	Amoxicillin; Clarithromycin; Omeprazole.	500 mg, n/a, n/a; n/a, 500 mg, n/a; n/a, n/a, 20 mg.	Capsule, Tablet, Capsule, Delayed Release; Oral.	Cumberland Pharms.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 9, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-10296 Filed 5-12-23; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program; List of Petitions Received

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

**FOR FURTHER INFORMATION CONTACT:** For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357-6400. For information on HRSA’s role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443-

6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

**SUPPLEMENTARY INFORMATION:** The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in

the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.” Set forth below is a list of petitions received by HRSA on March 1, 2023, through March 31, 2023. This list provides the name of the petitioner, city, and state of vaccination (if unknown then the city and state of the person or attorney filing the claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following:

1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and

2. Any allegation in a petition that the petitioner either:

a. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by” one of the vaccines referred to in the Table, or

b. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine” referred to in the Table.

In accordance with section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Health Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857. The Court’s caption (*Petitioner’s Name v. Secretary of HHS*) and the docket number assigned to the

petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

**Carole Johnson,**  
*Administrator.*

#### List of Petitions Filed

1. Andrew Williamson, Shawnee Mission, Kansas, Court of Federal Claims No: 23–0301V
2. Hoberleigh Nicholson, Bowling Green, Kentucky, Court of Federal Claims No: 23–0302V
3. David Kiss, Malvern, Pennsylvania, Court of Federal Claims No: 23–0304V
4. Nancy Hardy, Dallas, Texas, Court of Federal Claims No: 23–0305V
5. Fredrick T. Pollard, Redgranite, Wisconsin, Court of Federal Claims No: 23–0307V
6. Brian Bieber, Sioux Falls, South Dakota, Court of Federal Claims No: 23–0309V
7. Haley Ferguson, Phoenix, Arizona, Court of Federal Claims No: 23–0312V
8. Jennifer Teeter, Johnstown, Pennsylvania, Court of Federal Claims No: 23–0313V
9. Reba Lopez, Milwaukee, Wisconsin, Court of Federal Claims No: 23–0315V
10. Amanda Soliz, Boston, Massachusetts, Court of Federal Claims No: 23–0316V
11. Heather Jowett, Detroit, Michigan, Court of Federal Claims No: 23–0317V
12. Ashley Jennings, Independence, Missouri, Court of Federal Claims No: 23–0318V
13. David Deocampo, Blue Ash, Ohio, Court of Federal Claims No: 23–0319V
14. Aynabeba Singh, Howell, New Jersey, Court of Federal Claims No: 23–0323V
15. Dawn Guerrero, North Babylon, New York, Court of Federal Claims No: 23–0325V
16. Kristin Maeckel, Alpharetta, Georgia, Court of Federal Claims No: 23–0326V
17. Jenny Neidig, Sunbury, Pennsylvania, Court of Federal Claims No: 23–0327V
18. Heidi Flanagan, Oakland, California, Court of Federal Claims No: 23–0328V
19. Charlotte J. Bridges, Morganton, North Carolina, Court of Federal Claims No: 23–0329V
20. Gayle Duncan, Lutherville-Timonium, Maryland, Court of Federal Claims No: 23–0331V
21. Austen Walker, San Antonio, Texas, Court of Federal Claims No: 23–0333V
22. Randall Steffens, Weimar, California, Court of Federal Claims No: 23–0336V
23. Gayle McKay, Houston, Texas, Court of Federal Claims No: 23–0337V
24. Matthew Gudorf, Uhrichsville, Ohio, Court of Federal Claims No: 23–0342V
25. Mashonda Graham, Granite City, Illinois, Court of Federal Claims No: 23–0344V
26. Brian Reese, La Mesa, California, Court of Federal Claims No: 23–0345V
27. Dale Prindle, Wauconda, Illinois, Court of Federal Claims No: 23–0346V
28. Linda Johnson on behalf of the Estate of Joseph Johnson, Sr., Deceased, Covington, Louisiana, Court of Federal

- Claims No: 23–0347V
29. Josephine Corban, Boston, Massachusetts, Court of Federal Claims No: 23–0349V
30. Cheryl Weakley, San Diego, California, Court of Federal Claims No: 23–0350V
31. Diane Fisher, Woodbridge, Illinois, Court of Federal Claims No: 23–0352V
32. Charleigh Gadd, Phoenix, Arizona, Court of Federal Claims No: 23–0353V
33. Olivia Warpula, Phoenix, Arizona, Court of Federal Claims No: 23–0354V
34. David Krube, Boston, Massachusetts, Court of Federal Claims No: 23–0355V
35. Lauren Blinder, Lakeland, Florida, Court of Federal Claims No: 23–0356V
36. Christa Leininger, Kansas City, Missouri, Court of Federal Claims No: 23–0357V
37. Charlie Booth, Clackamas, Oregon, Court of Federal Claims No: 23–0358V
38. Linda Ruocco, Mount Vernon, New York, Court of Federal Claims No: 23–0360V
39. Elizabeth Soriano, Santa Clara, California, Court of Federal Claims No: 23–0362V
40. Chris Watson, North Kansas City, Missouri, Court of Federal Claims No: 23–0364V
41. Gwendolyn Giorgi, Providence, Rhode Island, Court of Federal Claims No: 23–0365V
42. Pearlene Derello, Mebane, North Carolina, Court of Federal Claims No: 23–0366V
43. Marna Harmon, Ottawa, Illinois, Court of Federal Claims No: 23–0367V
44. April Chesnutt-Kriss, St. Louis, Missouri, Court of Federal Claims No: 23–0368V
45. Laureen Usina, Fort Wayne, Indiana, Court of Federal Claims No: 23–0369V
46. Kaitlyn Sorby, Las Vegas, Nevada, Court of Federal Claims No: 23–0370V
47. Joya Wotila, Southlake, Texas, Court of Federal Claims No: 23–0371V
48. Suzanne C. Anderson, Bangor, Maine, Court of Federal Claims No: 23–0373V
49. Diana Smith, Menlo Park, California, Court of Federal Claims No: 23–0375V
50. Barbara Dorsett, Sacramento, California, Court of Federal Claims No: 23–0377V
51. Joan Barclay, Babylon, New York, Court of Federal Claims No: 23–0378V
52. Hannah Huie, Phoenix, Arizona, Court of Federal Claims No: 23–0379V
53. Renee Rini, Albuquerque, New Mexico, Court of Federal Claims No: 23–0380V
54. Kenneth Arrington, Boston, Massachusetts, Court of Federal Claims No: 23–0381V
55. Rekha Kumar, Arcadia, California, Court of Federal Claims No: 23–0382V
56. Charlie Benedick, Casper, Wyoming, Court of Federal Claims No: 23–0384V
57. Al Raya, Bedford, Virginia, Court of Federal Claims No: 23–0385V
58. Steve Cantalupo on behalf of A.C., Phoenix, Arizona, Court of Federal Claims No: 23–0388V
59. Muriel Childs, Dyer, Indiana, Court of Federal Claims No: 23–0389V
60. Elizabeth Sanchez Denton, Dan Diego, California, Court of Federal Claims No: 23–0390V
61. Matthew Iroku, Phoenix, Arizona, Court of Federal Claims No: 23–0395V
62. Marcia Rea, Woodland Hills, California, Court of Federal Claims No: 23–0397V
63. Kimberly Uribe, Haslett, Michigan, Court

- of Federal Claims No: 23–0398V
64. Karey Dunaway, Dublin, Ohio, Court of Federal Claims No: 23–0400V
65. Lisa McMurtry on behalf of M.M., Phoenix, Arizona, Court of Federal Claims No: 23–0404V
66. Barbara Glover, Elm City, North Carolina, Court of Federal Claims No: 23–0406V
67. Kim Leone, Boston, Massachusetts, Court of Federal Claims No: 23–0407V
68. Alexa Flores, Phoenix, Arizona, Court of Federal Claims No: 23–0408V
69. Richard Liebell, Boston, Massachusetts, Court of Federal Claims No: 23–0409V
70. Michelle Wombold, Gainesville, Florida, Court of Federal Claims No: 23–0410V
71. Joanne Costello, New Milford, Connecticut, Court of Federal Claims No: 23–0411V
72. Mackenzie Gardett, Phoenix, Arizona, Court of Federal Claims No: 23–0412V
73. Leslie Sager, Seattle, Washington, Court of Federal Claims No: 23–0413V
74. Crystal Morefield on behalf of A.J., Phoenix, Arizona, Court of Federal Claims No: 23–0414V
75. Shelly Simms on behalf of R.S., Phoenix, Arizona, Court of Federal Claims No: 23–0419V
76. Courtney Ball, London, Ohio, Court of Federal Claims No: 23–0420V
77. Cara Fowler, Westerville, Ohio, Court of Federal Claims No: 23–0421V
78. Ian Bruening, Cumming, Georgia, Court of Federal Claims No: 23–0422V
79. Lori Wigler, New York City, New York, Court of Federal Claims No: 23–0426V
80. Michael Veystel, Newark, New Jersey, Court of Federal Claims No: 23–0428V
81. Kevin Charles McIntosh, Grants Pass, Oregon, Court of Federal Claims No: 23–0429V
82. Madeleine Karol, San Diego, California, Court of Federal Claims No: 23–0432V
83. Clarissa Olive, Phoenix, Arizona, Court of Federal Claims No: 23–0435V
84. Teresa Farias, Mission, Texas, Court of Federal Claims No: 23–0436V

85. Dora Homann, Huntersville, North Carolina, Court of Federal Claims No: 23–0437V
86. Tracy Barnhart on behalf of A.B., Lockport, Illinois, Court of Federal Claims No: 23–0439V
87. Wendy Hubbard, Houston, Texas, Court of Federal Claims No: 23–0440V
88. Nora Barron, Hoboken, New Jersey, Court of Federal Claims No: 23–0442V
89. Michael Stack, Tampa, Florida, Court of Federal Claims No: 23–0454V
90. Elizabeth Culhane, Greenwood, Michigan, Court of Federal Claims No: 23–0456V
91. Kimberly Sullivan on behalf of M.S., Phoenix, Arizona, Court of Federal Claims No: 23–0458V
92. Jan Holt on behalf of K.S., Phoenix, Arizona, Court of Federal Claims No: 23–0459V
93. Venetia Royster on behalf of M.L., Greensboro, North Carolina, Court of Federal Claims No: 23–0460V

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BILLING CODE 4165–15–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Regional AIDS Education and Training Centers Program Supplemental Award

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Announcing a Supplemental Award for Ryan White HIV/AIDS Program (RWHAP), Regional AIDS Education and Training Center (AETC) award recipient, University of Massachusetts (UMass).

**SUMMARY:** HRSA will provide supplemental funding to UMass, a current Regional AETC Program award recipient, for a 1-year period of performance and 1-year budget period to support a program designed to train internal and family medicine residents to specialize in HIV treatment and care management. This training program is critically needed, as it will help increase the number of primary HIV care providers available to diagnose, treat, and medically manage people with HIV and address urgent needs stemming from the HIV care workforce shortage.

**FOR FURTHER INFORMATION CONTACT:** Suzanne Abo, Management Analyst, Office of Program Support, HIV/AIDS Bureau, HRSA, at [sabo@hrsa.gov](mailto:sabo@hrsa.gov) and (301) 945–4537.

#### SUPPLEMENTARY INFORMATION:

*Intended Recipient(s) of the Award:* UMass, a Regional AETC Program award recipient that currently has the capacity and an existing program designed to train medical residents in HIV care to help increase the number of providers who can serve people with HIV and address the critical provider shortage.

*Amount of Non-Competitive Award:* One award for \$450,000.

*Project Period:* July 1, 2023, to June 30, 2024.

*Assistance Listing (CFDA) Number:* 93.145.

*Award Instrument:* Supplement for HIV/AIDS Workforce Development and Training Services.

*Authority:* Section 2692(a) (42 U.S.C. 300ff–111(a)) and section 2693 (42 U.S.C. 300ff–121) of the Public Health Service Act.

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Award amount
6 U1OHA29294–08–03 .....	University of Massachusetts .....	MA	\$450,000

*Justification:* The HIV care workforce continues to decrease, directly impacting the ability of RWHAP to meet the goals and objectives of the Ending the HIV Epidemic in the United States by 2030. Experts indicate that fewer medical trainees are entering the field of HIV and that workforce trends are not keeping pace with the rates of HIV infection. Given the overall HIV/AIDS care workforce challenges presented, it is imperative that purposeful action is taken to support the current workforce. According to a recent HIV care provider study conducted by the RWHAP National Coordinating Resource Center, in addition to the current workforce

shortages, 10.5 percent of the current providers surveyed will be leaving HIV care in 5 years, and an additional 7.3 percent of those surveyed will be decreasing the number of patients with HIV to whom they provide care.

In November 2022, UMass, a current award recipient of the Regional AETC Program, submitted an unsolicited proposal to HRSA's HIV/AIDS Bureau to support a program designed to train internal and family medicine residents to specialize in HIV care and management. The HIV Pathways Consortium Program (Pathways) is designed to increase the number of primary care providers that have the

knowledge and expertise to provide direct care services and treatment to people with HIV and train other primary care providers. UMass has implemented Pathways for several years and has been able to demonstrate impact on the HIV care workforce. Pathways aligns with the purpose and scope of work for the Regional AETC Program as described in the current Fiscal Year 2019 Notice of Funding Opportunity (HRSA 19–035).

The proposal underwent extensive review per the guidelines established by HHS and HRSA for a recipient initiated supplemental funding proposal. Having met the HHS guidelines, further review determined that the proposal aligns